

IN THE CLAIMS: See Listing of Claims. This listing will replace all prior versions of claims in the application.

REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 26-44 remain pending in the application; however, Claims 33-44 have been withdrawn from consideration as a result of the previously issued Restriction Requirement. The Office maintains this Restriction Requirement and makes it Final. The Office raises a rejection under 35 USC § 112, second paragraph, as well as a rejection under 35 USC § 103. The Office acknowledges the Information Disclosure Statement (IDS) filed with the filing papers of the instant application.

With respect to the Restriction Requirement, it remains the position of the Office that the shared common technical feature (i.e., a composition comprising an antioxidant agent and a mixed PPAR ligand) between Restriction **Groups I and II** does not define a contribution over the prior art and that, therefore, these groups lack unity of invention. The Applicants note that the Office has not included at least one method of treatment claim (i.e., obesity) for prosecution with the substance claims despite the Applicants' request (included with the Response and Election of June 13, 2008) for the inclusion of such a claim in accordance with PCT Rule 13.2. The Applicants respectfully reiterate this request. Moreover, in accordance with MPEP § 821.04, the Applicants also request rejoinder of method Claims 33-44 upon the identification of allowable subject matter.

Claims 27-30 are rejected for indefiniteness under 35 USC § 112, second paragraph. The Office states that Claims 27-30 recite the "composition of Claim 26" but that Claim 26 recites "a combination comprising a combination..." Therefore, it is the position of the Office that Claim 26 does not provide sufficient antecedent basis for dependent Claims 27-30. With the instant Amendment, Claim 26 has been amended to recite "a composition comprising a combination..." to provide the proper antecedent basis for dependent Claims 27-30. Reconsideration and withdrawal of the indefiniteness rejection is respectfully requested.

Claims 26-32 are rejected for obviousness under 35 USC § 103(a) based on the disclosure of Watts, et al. (International Publication No. WO 02/34259). The Office states that Watts, et al. disclose a composition comprising a peroxisome proliferator activated receptor (PPAR) activator and a benzoquinone. With respect to the disclosed PPAR activators, the Office states that Watts, et al. disclose that the PPAR activators may be activators of either PPAR α or PPAR γ and that a number of activators are known in the art, including the fibrate (e.g., bezafibrate) and thiazolinedione (e.g., rosiglitazone) classes of drugs. The Office goes on to state that Watts, et al. disclose that bezafibrate has been shown to activate both PPAR α and PPAR γ . With respect to the disclosed benzoquinones, the Office states that Watts, et al. disclose that such compounds have antioxidant properties and that the preferred benzoquinone is ubiquinone or coenzyme Q₁₀.

It is the position of the Office that based on the disclosure of Watts, et al., it would have been obvious to one skilled in the art to use bezafibrate (a mixed PPAR α and PPAR γ ligand) or a combination of rosiglitazone (a PPAR γ ligand) and fenofibrate (a PPAR α ligand) in combination with an antioxidant such as coenzyme Q₁₀ to arrive at the instantly claimed compositions. It is the further position of the Office that one skilled in the art would have been motivated to formulate such a composition since a composition comprising a PPAR ligand in combination with an antioxidant has been previously taught in the art to be useful for lowering triglycerides. Thus, the Office concludes that, based on this known activity, one skilled in the art would have had a reasonable expectation of success that compositions comprising a PPAR ligand and an antioxidant would be effective for treating conditions such as obesity and atherosclerosis.

The Applicants respectfully submit that the specification discloses the unexpected properties associated with the instantly claimed compositions. The data disclosed at pages 7-8 of the specification demonstrate that rosiglitazone alone causes weight gain in obese mice and that treatment with a combination of rosiglitazone and coenzyme Q₁₀ reverses this weight gain. Moreover, with the instant Response, the Applicants submit a Declaration by Dr. Catherine DACQUET, a scientist skilled in

this particular art, which speaks to the superior and unexpected effects associated with the instant compositions. Specifically, the Declarant provides pharmacological data which demonstrate that representative examples of the instantly claimed combinations produce significant weight loss in obese mice and that this weight loss is much greater than any weight loss produced by administration of a single component of the combination. These pharmacological data demonstrate the synergistic effects associated with the instantly claimed compositions. Thus, the Applicants respectfully submit that the instantly claimed compositions are not rendered obvious by the disclosure of Watts, et al. Reconsideration and withdrawal of the obviousness rejection under 35 USC § 103(a) is respectfully requested.

Finally, the Applicants note that the Examiner has not considered International Search Report (ISR) and International Preliminary Examination Report (IPER) which were included with the Information Disclosure Statement (IDS) submitted with the filing papers of the instant application. The Office states that these documents are not "published documents" and that, therefore, these documents do not have a publication date. The Applicants respectfully submit that the ISR and IPER are publicly available at the WIPO website, and that, therefore these documents are, in fact, a "publication" in the international equivalent of the instant application. A copy of the listing of these references from the WIPO website is enclosed. The Applicants respectfully request that the Office consider the previously submitted references.

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Accordingly, entry of the present amendment and the DACQUET Declaration, entry and acknowledgment of the previously submitted references, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.


It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding

insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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Enclosure: Check No. 76823 for Three (3) Month Extension Fee; DACQUET Declaration; Reference Listing from WIPO website; Previously Submitted ISR and IPER; Listing of Claims; and Postal Card Receipt

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.